



VA Directive 0005 on Scientific Integrity

AGENCY: Office of Policy and Planning, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: This Federal Register notice announces the adoption of the Department of Veterans Affairs (VA) Directive 0005 on Scientific Integrity and responds to public comments about the draft version of this Directive, which was originally announced in the Federal Register on April 9, 2012 (77 FR 21158).

FOR FURTHER INFORMATION CONTACT: Billy E. Jones, M.D., Senior Advisor to the Assistant Secretary for Policy and Planning (008), Department of Veterans Affairs, at 202-461-5762. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

Background

The Presidential Memorandum on Scientific Integrity and the Office of Science and Technology Policy's 2010 guidance memorandum on scientific integrity call for ensuring the highest level of integrity in all aspects of the Executive Branch's involvement with scientific and technological processes.

VA Policy on Scientific Integrity

VA Directive 0005 on Scientific Integrity, adopted on July 10, 2012, is available on the VA Publications Web site at <http://www1.va.gov/vapubs/>. Directive 0005 establishes VA policies that:

- Foster a culture of transparency, integrity, and ethical behavior in the development and application of scientific and technological findings in VA;
- Protect the development, application, and dissemination of scientific and technological information from political or commercial influence;
- Prohibit suppression or alteration of scientific and technological findings for political purposes;
- Afford whistleblower protections to employees who have scientific integrity concerns;
- Uphold professional and Governmental standards for the conduct for research;
- Promote free flow and exchange of scientific and technological information;
- Ensure that clinical care, health care operations, and public health decisions are informed by scientific data and analysis;
- Uphold the independence, transparency, and diversity of Scientific Advisory Committees; and
- Encourage full participation of employees in scientific and professional activities.

Public Comments on VA Draft Policy on Scientific Integrity

VA adopted Directive 0005 on Scientific Integrity after carefully reviewing and considering public comments that were received on the draft version of this Directive, which was announced in the Federal Register on April 9, 2012 (77 FR 21158). All of the public comments have been grouped together by the paragraph of the Directive that they address, and VA has organized our discussion of the comments accordingly. All comments are available for public inspection between the hours of 8 a.m. and 4:30 p.m.

in the Office of Regulation Policy and Management, Department of Veterans Affairs, 810 Vermont Avenue NW, Room 1063B, Washington, DC 20420. Call (202) 461-4902 for an appointment.

Comments

A. Purpose, Responsibilities, and Definitions (VA Directive 0005, ¶¶ 1 - 3)

Comment Summary: The Directive should apply to all VA employees, including VA scientists, managers, supervisors, visiting scientists, political appointees. The Directive should also apply to VA contractors.

VA Response: VA has amended the note in Directive 0005, ¶ 1, so that it clarifies that the Directive applies to all VA employees, thereby including all VA scientists, managers, supervisors, visiting scientists, and political appointees. All VA contracts are managed by VA employees. VA may share this Directive with the agency's contractors and may incorporate the policies in this Directive in applicable future contracts or when renewing existing contracts.

Comment Summary: The Directive should clearly define what constitutes a conflict of interest to strengthen disclosure of and reduce conflict of interest among, employees, and reviewers. Conflict of interest policies should apply to research staff as well as research investigators.

VA Response: As stated under Directive 0005, ¶ 5.a.(3), VA is currently developing conflict of interest requirements specifically applicable to research. These requirements will define what constitutes a research conflict of interest and who is

required to follow VA's conflict of interest requirements. Consequently, no changes were made to the Directive.

Comment Summary: VA should improve transparency by publicly reporting information on individuals who meet with top agency officials.

VA Response: This comment addresses an issue that is beyond the scope of VA Directive 0005. Consequently, no changes were made to the Directive.

B. Core Principles (VA Directive 0005, ¶ 4)

Comment Summary: It is not clear what constitutes "inappropriate influence." The definition of "inappropriate influence" should be more explicit.

VA Response: VA has amended Directive 0005, ¶ 4.b.(3), so that it explicitly state's that scientific data and analyses will be protected from political and commercial influence. The term "inappropriate influence" has been removed.

C. Foundations of Scientific Integrity (VA Directive 0005, ¶ 5)

Comment Summary: The Directive should provide clear and specific guidelines relating to the enforcement, reporting, and investigation of allegations related to scientific integrity violations. Uncensored details of cases should be provided to the VA's Office of Inspector General (OIG), the Office of Government Ethics, and Congress. VA should create an online portal where all documents related to scientific integrity may be found. VA should have a Department-wide procedure for reporting and investigating allegations related to scientific integrity violations.

VA Response: VA has amended Directive 0005, ¶ 5.a.(8), so that it discusses the Veterans Health Administration's (VHA) Office of Research Oversight's statutory authority, under 38 U.S.C. § 7307, to investigate and enforce compliance with VA requirements for the conduct of research, including research misconduct and other forms of research impropriety. VHA's Office of Research Oversight (ORO) operates independently of all VA entities that fund research and may suspend VA research where warranted. All VHA Directives and Handbooks related to scientific integrity, including the procedures for reporting allegations to ORO and the standards for ORO's investigation and enforcement activities and may be found on the ORO Web site at <http://www.va.gov/oro/>. The ORO Web site provides guidance on filing a complaint and includes a telephone hotline for persons who wish to remain anonymous. In accordance with statutory requirements, ORO reports all of its activities, investigations, and findings to the Committees on Veterans' Affairs of the United States Senate and House of Representatives. ORO regularly exchanges information with OIG, including summaries of all compliance cases and copies of all compliance reports.

Comment Summary: Whistleblower protections should be strengthened to prohibit individuals from recommending or taking a personnel action as a means of censoring or discriminating against an employee or grant applicant because the employee or grant applicant discloses, or is about to disclose, information that he or she believes is evidence of illegality.

VA Response: As stated under Directive 0005, ¶ 5.a.(10), VA will afford whistleblower protections to employees who have a reasonable belief of scientific integrity concerns, including but not limited to, the protections described in 5 U.S.C. §

2302, which specifically prohibit threatening, taking, or not taking personnel actions against an employee (or applicant for employment) who discloses information reasonably believed to be a violation of law, rule, or regulation or to represent gross mismanagement, waste of public funds, abuse of authority, or substantial and specific danger to public health or safety. These employee protections are sufficient for VA because VA does not award research grants to individuals who are not VA employees. Consequently, no changes were made to the Directive.

Comment Summary: VA employees should have the right to review, approve, and comment on the final version of any proposed publication that significantly relies on their research, identifies them as an author or contributor, or purports to represent their scientific opinion. Procedures should be established for handling differing scientific opinions and ensuring that these opinions are included in the final versions of scientific documents.

VA Response: VA has amended Directive 0005, ¶ 5.e.(1), to clarify that VA employees who conduct research independently determine the content of publications that report on their research findings. The primary author of such publications is responsible for interpreting the findings and ensuring the accuracy of the findings reported. Disputes may be referred to the study sponsor, the VHA Office of Research and Development, or ORO, depending upon the nature of the dispute. Publications of findings from VA research are submitted to peer reviewed journals, and the peer review process ensures that differing opinions on the interpretation of findings are considered. Consequently, no changes were made to the Directive.

Comment Summary: The Directive should not state that “every aspect of VA research . . . is governed by specific regulations, policies and guidelines” since not every aspect of VA research can be governed by regulations, policies, or guidelines.

VA Response: VA has amended Directive 0005, ¶ 5.b., to state that “VA policy provides an ethical and accountable framework in the form of specific regulations, policies, and guidelines that establish VA’s research priorities, funding mechanisms, administration, conduct, and oversight.”

Comment Summary: Protections related to research safety should also extend to research staff.

VA Response: VA has amended Directive 0005, ¶ 5.b.(4), so that it explicitly includes research safety protections for research staff.

Comment Summary: The Directive should clarify whether VA’s policy is to ensure the privacy and confidentiality of research data and research-related information.

VA Response: VA has amended Directive 0005, ¶ 5.b.(5), so that it specifically includes ensuring the privacy and confidentiality of research data as well as research-related information.

Comment Summary: VA needs to demonstrate how it will make VA research findings and the products of VA research available to the public.

VA Response: As stated under Directive 0005, ¶¶ 5.e.(1) and 5.e.(2), VA will convey research findings to the public in a timely, accurate, and comprehensive

manner. VA is currently developing formal policies to promote the sharing of VA research findings to the public. Consequently, no changes were made to the Directive.

Comment Summary: VA should replace the Association for the Accreditation of Human Research Protection Programs (AAHRPP) with Alion Science and Technology Corporation and clarify requirements relative to the accreditation of VA facility human research protection programs.

VA Response: VA is currently reviewing its accreditation requirements and in the interim has removed AAHRPP's name from the Directive.

D. Public Communications (Directive 0005, ¶ 6)

Comment Summary: The phrase requiring “appropriate coordination” by research investigators in speaking to the media is too ambiguous.

VA Response: VA has deleted the word “appropriate” from Directive 0005 ¶ 6.a. to eliminate the ambiguity and ensure consistency with ¶ 6.a.(7).

Comment Summary: The policy should explicitly state that scientists have the right to express their own views so long as the appropriate disclaimers are made. Public affairs officials should not interfere with this right.

VA Response: VA has amended the note in Directive 0005, ¶ 6.a.(5), to state that VA scientists and other VA employees may express their personal views to the media provided that they specify that they are speaking in their private capacity and not speaking on behalf of VA.

E. Use of Federal Advisory Committees (Directive 0005, ¶ 7)

Comment Summary: The Directive should reduce conflicts of interest among, employees, reviewers, and members of Federal advisory committees.

VA Response: VA is currently developing conflict of interest requirements specifically applicable to research. Consequently, no changes were made to the Directive.

F. Professional Development (Directive 0005, ¶ 8)

Comment Summary: VA scientists should be required to disclose conflicts of interest if they participate in scientific societies or sit on their boards.

VA Response: VA has amended the note in Directive 0005, ¶ 8.a.(4), to clarify that participation in professional societies is encouraged, to the extent permitted by law and in accordance with the Standards of Professional Conduct for Employees of the Executive Branch.

Comment Summary: VA should have regular training in scientific integrity for all of its employees.

VA Response: As stated under Directive 0005, ¶ 8.c., VA researchers are required to complete training at 2-year intervals in multiple areas, including data integrity, ethics, privacy, and human research protections, as well as training in specific content areas relevant to their research. Consequently, no changes were made to the Directive.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on November 5, 2012, for publication.

Dated: November 5, 2012

Robert C. McFetridge,
Director, Regulation Policy and Management,
Office of the General Counsel,
Department of Veterans Affairs.

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